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MAR 2 1 2002

LICOX® CC1.G2 Brain Oxygen Catheter-MicroProbe

510(k) SUMMARY

Submitter's name and address:

Integra NeuroSciences
311 Enterprise Drive
Plainsboro, NJ 08536

Contact person and telephone number:

Nancy A. Mathewson, Esq.
Director, Regulatory Affairs
(858) 455-1115

Date summary was prepared:

February 19, 2002

Name of the device:

Proprietary Name:	LICOX® Brain Oxygen Monitoring System LICOX® CC1.G2 Brain Oxygen Catheter-MicroProbe
Common Name:	Brain oxygen monitoring device
Classification Name:	Intracranial Pressure Monitoring Device, 21 CFR 882.1620, 84GWM
Classification Panel:	Neurology Device Panel

Substantial Equivalence:

The LICOX® CC1.G2 product was designed to have the same indications for use and perform to the same specifications as the LICOX® CC1.SB Brain Oxygen Catheter-Microprobe (510(k) K002765).

Device Description:

The LICOX® CC1.G2 is a brain oxygen catheter-microprobe intended for use with the LICOX Brain Oxygen Monitoring System. The LICOX Brain Oxygen Monitoring System measures intracranial oxygen and temperature. The probe is used in conjunction with the LICOX® CMP Monitor and it's associated accessories and cables.

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Statement of Intended Use:

The LICOX® CC1.G2 is a brain oxygen catheter-microprobe intended for use with the LICOX Brain Oxygen Monitoring System. The LICOX Brain Oxygen Monitoring System measures intracranial oxygen and temperature and is intended as an adjunct monitor of trends of these parameters, indicating the perfusion status of cerebral tissue local to sensor placement. LICOX System values are relative within an individual, and should not be used as the sole basis for decisions as to diagnosis or therapy. It is intended to provide data additional to that obtained by current clinical practice in cases where hypoxia or ischemia are a concern.

Comparison of technological characteristics to the predicate device:

Parameter	LICOX® CC1.SB	LICOX® CC1.G2
Indications for Use	The LICOX® CC1.G2 is a brain oxygen catheter-microprobe is intended for use with the LICOX Brain Oxygen Monitoring System. The LICOX Brain Oxygen Monitoring System measures intracranial oxygen and temperature and is intended as an adjunct monitor of trends of these parameters, indicating the perfusion status of cerebral tissue local to sensor placement. LICOX System values are relative within an individual, and should not be used as the sole basis for decisions as to diagnosis or therapy. It is intended to provide data additional to that obtained by current clinical practice in cases where hypoxia or ischemia are a concern.	Identical to the LICOX® CC1.SB
Anatomical Site	Brain parenchyma	Identical to the LICOX® CC1.SB
Target Population	Head trauma, craniotomy, with possible hypoxia or ischemia.	Identical to the LICOX® CC1.SB
Parameters	Brain pO_2	Identical to the LICOX® CC1.SB
Sterility	Sterile	Identical to the LICOX® CC1.SB
Single-use	Yes	Identical to the LICOX® CC1.SB
Monitoring duration	5 days	Identical to the LICOX® CC1.SB
Tissue contacting material	Polyethylene	Identical to the LICOX® CC1.SB

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Parameter	LICOX® CC1.SB	LICOX® CC1.G2
O_2 Sensing technology	Clark Cell	Identical to the LICOX® CC1.SB
Calibration	Smart Card calibrated to each oxygen sensor during manufacture, Smart Card read by monitor at time of use	Identical to the LICOX® CC1.SB
In Vitro Accuracy, pO_2	±2.0mmHg (0-20 mm Hg) ±10% (21 mm Hg-50 mm Hg) ±12% > 51 mm Hg	Identical to the LICOX® CC1.SB
System monitor	LICOX CMP Monitor and associated accessories and cables	Identical to the LICOX® CC1.SB
Packaging Method and Materials	Double blister tray (PETG with Tyvek lid) placed in a chevron pouch made of Flexovac (polyester/polyethylene) foil with uncoated paper.	Identical to the LICOX® CC1.SB
Sterilization Process	Gamma Radiation to a sterility assurance level of 10^{-6}.	Identical to the LICOX® CC1.SB

Safety:

Biocompatibility studies were conducted per FDA G95-1 and ISO 10993 and have demonstrated that the materials used to manufacture the LICOX® CC1.G2 catheter are safe for its intended use.

In addition, the LICOX® CC1.G2 catheter was subjected to extensive oxygen pressure measurement accuracy testing.. Results of the testing showed that the catheter design met all accuracy specifications.

The LICOX® CC1.G2 manufacturing process complies with the United States Food and Drug Administration and European Standards for the manufacturing of medical devices.

Conclusion:

The LICOX® CC1.G2 Brain Oxygen Catheter-MicroProbe is substantially equivalent to the unmodified LICOX® CC1.SB Brain Oxygen Catheter-MicroProbe. The modifications do not affect the intended use or the fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2002

Ms. Nancy A. Mathewson
Director, Regulatory Affairs
Integra NeuroSciences
5955 Pacific Center Boulevard
San Diego, CA 92121-4309

Re: K020558
Trade/Device Name: LICOX® CC1.G2 Brain Oxygen Catheter-MicroProbe
Regulation Number: 882.1620
Regulation Name: Intracranial pressure monitoring device
Regulatory Class: II
Product Code: GWM
Dated: February 19, 2002
Received: February 20, 2002

Dear Ms. Mathewson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX B

Indications for Use Statement

510(k) Number K020558

Device Name LICOX® CC1.G2 Brain Oxygen Catheter-MicroProbe

Indications for Use

The LICOX® CC1.G2 is a brain oxygen catheter-microprobe intended for use with the LICOX Brain Oxygen Monitoring System. The LICOX Brain Oxygen Monitoring System measures intracranial oxygen and temperature and is intended as an adjunct monitor of trends of these parameters, indicating the perfusion status of cerebral tissue local to sensor placement. LICOX System values are relative within an individual, and should not be used as the sole basis for decisions as to diagnosis or therapy. It is intended to provide data additional to that obtained by current clinical practice in cases where hypoxia or ischemia are a concern.

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020558

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)